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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,575	02/09/2001	Thomas J. Kodadck	UTSD:566US/SLH	1617

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EXAMINER

CELSA, BENNETT M

ART UNIT PAPER NUMBER

1639

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,575

Applicant(s)

KODADEK, THOMAS J.

Examiner

Bennett Celsa

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Claims 1-39 are currently pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, 22-26 and 29-30, drawn to a peptide ligand/peptide receptor assay, classified in class 436, subclass 501.
 - II. Claims 16-17, drawn to a mutated peptide ligand/peptide receptor assay, classified in class 435, subclass 440.
 - III. Claims 18-21 and 27-28, drawn to a "stabilized" (e.g. cross linked/phototrapped) ligand/peptide receptor assay, classified in class 435, subclass 7.6.
 - IV. Claims 31-34, drawn to the screening of a library of peptide ligands with a library of peptide receptors, classified in class 435 , subclass 5.
 - V. Claim 35 is drawn to a library encoded peptide , classified in class 530, subclass 300.
 - VI. Claims 36-39, drawn to conjugated heterodimeric peptide, classified in class 530, subclass 350+ and class 424, subclass 192.1.

2. The inventions are distinct, each from the other because of the following reasons:

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3. Inventions I-IV are directed to different assays that are patentably distinct due to differences in method objective and the use of patentably distinct ligands (e.g. underivatized versus derivatized as mutants, conjugates, phototrapped etc.) or the use of libraries of ligands which entails different reaction conditions and screening protocols. Additionally, the different methods require different and separately burdensome bibliographic manual/computer patent and literature searches.

4. Inventions V and VI are directed to patentably distinct compound claims due to different in the compositional structure of the peptides of Group V as compared to the conjugated heterodimers of Group VI which results in compounds possessing different physical/chemical/biological properties and which are capable of separate manufacture and/or use. Additionally, the different compounds require different and separately burdensome bibliographic/sequence manual/computer patent and literature searches.

5. Inventions (V or VI) and (I or II or III or IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product as illustrated in the Group I-IV inventions which utilize peptide ligands of different structure and conformation to achieve peptide receptor binding. Additionally, the product (s) (e.g. of Groups V or VI) as claimed can be used in a materially different process of using that product such as affinity purification of the receptor.

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6. Because these inventions are distinct for the reasons given above and:
- a. have acquired a separate status in the art as shown by their different classification;
 - b. the bibliographic/sequence/classification search required for the different Groups is different; and/or
 - c. the subject matter of the different Groups have acquired a separate status in the art because of their recognized divergent subject matter,
- restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES (FOR GROUPS I-VI)

7. This application contains claims directed to the following patentably distinct species of the claimed invention: SPECIES OF:

- | | |
|--|--------------|
| A. "Target Peptide" (enzyme substrate, specific antigen, specific multimer | (All |
| Groups) | |
| B. "1st DNA binding domain" (e.g. gamma repressor etc.) | (All |
| Groups) | |
| C. "Library Encoded Peptide" | (Groups I,II |
| D. "2nd DNA binding domain" (e.g. gamma repressor) | (All |
| Groups) | |
| E. "Indicator Polypeptide" (b gal etc) | (All Groups) |
| F. "Prokaryotic Operator Region" (e.g. lacZ | (All |
| Groups) | |
| G. "3rd Peptide" | (Group III) |

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H. "Stabilizing Interaction" (e.g. cross linking, phototrapping)

(Group III)

See specification for exemplified species of A-H above.

The species described in categories A-H above are directed to different and patentably distinct compounds, with different properties, which are capable of separate manufacture and/or use and which require different and separately burdensome manual and/or computer searches.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (**EG a SPECIFIC COMPOUND**) for the above A-H categories for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Future Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
March 12, 2004

Handwritten signature of Bennett Celsa, consisting of two lines of cursive script. The first line appears to be 'Bennett' and the second line appears to be 'Celsa'.